

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF
OBSTETRICIANS AND
GYNECOLOGISTS, *et al.*,

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

CIV. NO. 20-1320

**PLAINTIFFS' SUPPLEMENTAL BRIEFING ON *JUNE MEDICAL SERVICES V.*
RUSSO IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION**

I. INTRODUCTION

On June 29, for the second time in four years, the Supreme Court struck down an abortion regulation purportedly designed to protect patients' health, in a case brought by abortion clinics and physicians to vindicate their patients' constitutional rights. Applying the principles articulated in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), and the decades of jurisprudence on which it relied, a majority of the Court concluded in *June Medical Services, L.L.C. v. Russo* that a Louisiana law requiring abortion providers to have hospital admitting privileges imposed an unconstitutional undue burden. Nos. 18-1323, 18-1460, 2020 WL 3492640, at *4, *20-21 (U.S. June 29, 2020); *id.* at *22, *26, *29 (Roberts, C.J., concurring). The decision affirms that Defendants' legal analysis is wrong on multiple grounds and definitively supports Plaintiffs' motion for a preliminary injunction.

II. ARGUMENT

June Medical brings the flaws in Defendants' legal arguments into stark relief. Defendants argue that third-party standing is improper despite 40 years of precedent authorizing clinicians to raise their patients' constitutional right to abortion. *See* ECF No. 62 ("Defs.' Br.") 9-10; ECF No. 73 ("Pls.' Reply") 6-8. *June Medical* considers and rejects the same arguments. Defendants construe the undue burden test as singularly focused on whether a challenged law blocks patients from accessing abortion altogether—removing from the scale any balancing of the law's asserted benefits, any consideration of burdens beyond outright prevention, and, indeed, any burdens specific to medication abortion care at all. *See* Defs.' Br. 13-22; Pls.' Reply 8-16. This framing cannot be squared with *June Medical*, which preserves *Whole Woman's Health's* holdings—including the essential balancing test—and considers a range of burdens on abortion patients short of a complete bar, including health risks, delay, and impeded access to

medication abortion. Finally, Defendants argue that this Court should apply *United States v. Salerno*'s no-set-of-circumstances test instead of the large fraction test the Supreme Court has repeatedly applied in evaluating restrictions on abortion. 481 U.S. 739 (1987); *see* Defs.' Br. 11-13; Pls.' Reply 15 n.14. *June Medical* expressly rejects the argument that *Salerno* applies and instead again applies the large fraction test for facial invalidation, putting Defendants' argument decisively to bed. Because Defendants' key legal arguments—regarding third-party standing, Plaintiffs' likelihood of success on the merits of their privacy claim, and the standard for facial relief—are unsalvageable after *June Medical*, preliminary injunctive relief is warranted.

A. Third-Party Standing

June Medical reaffirms that abortion providers have standing to assert their patients' rights in constitutional challenges to abortion restrictions. 2020 WL 3492640, at *8-10 (plurality); *id.* at *26 n.4 (concurrence agreeing with plurality's entire discussion of standing). In addition to finding that the State had waived its third-party standing argument, the Court held that the State's standing challenge was also "foreclose[d]" by "a long line of well-established precedents." *Id.* at *10. The Court first observed that it "ha[s] long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations." *Id.* at *9 (citing nine Supreme Court decisions as examples). And noting that the Louisiana law—like the REMS—"regulates [abortion providers'] conduct," *id.* at *10, the Court explained that it also "ha[s] generally permitted plaintiffs to assert third-party rights in cases where the enforcement of the challenged restriction against the litigant would result indirectly in the violation of third parties' rights," *id.* at *9 (internal marks and emphasis omitted) (citing eight Supreme Court decisions as examples). Like the Louisiana physicians prohibited from providing abortion care unless they obtained admitting privileges, Plaintiffs and their members—who are

prohibited from providing medication abortion care unless they comply with the REMS’s clinician certification, in-person dispensing, and patient form requirements—are “obvious” and “uniquely qualified” representatives of their patients’ rights. *See id.* at *10; ECF No 1, Ex. 2, at 3 (mifepristone sponsors “must” “de-certify healthcare providers who do not maintain compliance” with the REMS and may “[n]ot ship mifepristone” to de-certified prescribers).

Moreover, *June Medical* rejected the arguments Defendants assert here to try to persuade this Court to break with precedent. A majority of the *June Medical* Court disagreed with Louisiana (and the dissent) that a disqualifying “conflict of interest” exists when the asserted justification for an abortion restriction is patient safety, noting that this “is a common feature of cases in which [the Court has] found third-party standing.” *Compare id.* at *10, *with id.* at *38, *49-50 (Alito, J., dissenting); Defs.’ Br. 10. Likewise, Louisiana’s argument that pregnant people seeking time-sensitive medical care do not face hindrances in directly litigating their rights found no traction with the *June Medical* majority. *Cf. June Med. Servs.*, 2020 WL 3492640, at *51-52 (Alito, J., dissenting); Defs.’ Br. 9. As the Court explained in *Singleton v. Wulff*, on which *June Medical* relies, *see June Med. Servs.*, 2020 WL 3492640, at *10, the key question on third-party standing is whether the litigant will be an effective advocate of the third-party’s rights, 428 U.S. 106, 114-18 (1976). Here, Plaintiffs and their members, who seek to protect their patients (and themselves) from the viral risks associated with unnecessary travel and in-person contact during the COVID-19 pandemic, are exactly the kind of effective advocates for their patients’ rights that the Supreme Court has once again recognized have third-party standing.

B. Undue Burden Standard

1. Consideration of Benefits

In *June Medical*, five Justices held that under *Whole Woman’s Health*, Louisiana’s

admitting privileges requirement for abortion providers is unconstitutional. As in *Whole Woman's Health*, the plurality “weigh[ed] the [Louisiana] law’s ‘asserted benefits against the burdens it imposes’ on abortion access,” and found those burdens undue. *June Med. Servs.*, 2020 WL 3492640, at *3-4 (quoting 136 S. Ct. at 2310) (describing *Whole Woman's Health*’s balancing test); *see also, e.g., id.* at *10-12 (affirming district court’s conclusion that, “even if [the Louisiana law] could be said to further women’s health to some marginal degree, the burdens it imposes far outweigh any such benefit”). Based on its review of the district court’s fact findings “both as to burdens and as to benefits,” the plurality agreed with the “determination that Louisiana’s law poses a ‘substantial obstacle’ to women seeking an abortion . . . offers no significant health-related benefits; and . . . that the law *consequently* imposes an ‘undue burden’ on a woman’s constitutional right to choose to have an abortion.” *Id.* at *20 (emphasis added).

Chief Justice Roberts reached the same result—that Louisiana’s law was unconstitutional—by applying the “principles of *stare decisis*.” *Id.* at *26 (Roberts, C.J., concurring); *id.* at *21-22. The Chief Justice explained that “[t]he question today . . . is not whether *Whole Woman's Health* was right or wrong, but whether to adhere to it in deciding the present case.” *Id.* at *21. Because *June Medical* involved a challenge “nearly identical to the Texas law struck down four years ago in *Whole Woman's Health*,” the Chief Justice determined that “the result in this case [was] controlled” by that decision. *Id.* at *21, *29; *see also id.* at *28 n.6 (“I cannot view the record here as in any pertinent respect sufficiently different from that in *Whole Woman's Health* to warrant a different outcome”).

It is of no moment that Chief Justice Roberts’s concurrence included a critique of the balancing test set forth and applied in *Whole Woman's Health*. *See id.* at *23-26. Defendants’ attempt to argue that the single-Justice concurrence overruled *Whole Woman's Health*’s

balancing test and relieves this Court of its obligation to “consider the burdens a law imposes on abortion access together with the benefits those laws confer,” *Whole Woman’s Health*, 136 S. Ct. at 2309, fails as a matter of law.

Under *Marks v. United States*, when a decision of the Court lacks a majority opinion, the opinion of the Justices concurring in the judgment on the “narrowest grounds” is regarded as the Court’s holding. 430 U.S. 188, 193 (1977). As the Fourth Circuit has explained, “the narrowest opinion [is one that] represents a common denominator of the Court’s reasoning’ and ‘embod[ies] a position implicitly approved by at least five Justices who support the judgment.’” *A.T. Massey Coal Co. v. Massanari*, 305 F.3d 226, 236 (4th Cir. 2002) (citing *Ass’n of Bituminous Contractors, Inc. v. Apfel*, 156 F.3d 1246, 1254 (D.C. Cir. 1998)).¹ The narrowest grounds constituting a “common denominator” of the Court’s reasoning must be a “logical subset” of the plurality opinion: to hold otherwise would turn *Marks* on its head and make the rationale garnering the *least* support among those supporting the judgment the law of the land. *See King*, 950 F.2d at 781; *Cardenas v. United States*, 826 F.3d 1164, 1171 (9th Cir. 2016) (“*Marks* applies when, for example, the concurrence posits a narrow test to which the plurality must *necessarily agree as a logical consequence* of its own, broader position.” (internal quotation marks and citation omitted) (emphasis in original)).

Here, the concurrence stands alone among “Justices who support the judgment” in

¹ Because courts are “controlled by the decisions of the Supreme Court,” and “[d]issenters, by definition, have not joined the Court’s decision,” their opinions are irrelevant to the *Marks* analysis. *United States v. Robison*, 505 F.3d 1208, 1221 (11th Cir. 2007); *see also, e.g., King v. Palmer*, 950 F.2d 771, 783 (D.C. Cir. 1991) (*en banc*) (“[W]e do not think we are free to combine a dissent with a concurrence to form a *Marks* majority.”); *Miller v. Brown*, 503 F.3d 360, 366 n.6 (4th Cir. 2007) (applying *Marks*, refusing to adopt the “concurring Justices’ view regarding the importance of the associational interests at stake” in *Clingman v. Beaver*, 544 U.S. 581 (2005), though the *Clingman* dissenters likewise found meaningful associational interests).

questioning the benefits-burdens balancing test. Far from “implicitly approv[ing]” that reasoning, the four Justices in the *June Medical* plurality reaffirmed and applied *Whole Woman’s Health’s* balancing test. *See supra* 4. Because the Chief Justice’s critique of the balancing test is not a “logical subset” of the plurality opinion and therefore cannot form the controlling opinion of the Court, this Court remains bound by the majority opinion in *Whole Woman’s Health*—which held that precedent “*requires* that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer.” *Whole Woman’s Health*, 136 S. Ct. at 2309 (emphasis added); *see also id.* at 2310-12 (evaluating benefits of challenged law before turning to question of burdens); *id.* at 2315-16 (same); *June Med. Servs.*, 2020 WL 3492640, at *3 (plurality describing balancing test as part of *Whole Woman’s Health’s* holding). The narrow controlling decision in *June Medical*—that the Louisiana admitting privileges law must fall under *Whole Woman’s Health*—does not alter this binding precedent. *See June Med. Servs.*, 2020 WL 3492640, at *21 (Roberts, C.J., concurring) (“[T]he question today . . . is whether to adhere to [*Whole Woman’s Health*] in deciding the present case”).

As Plaintiffs have explained, the Mifepristone In-Person Dispensing Requirement provides no benefit—none—and is opposed by the nation’s leading medical authorities; thus, the medical risk and other serious burdens the Requirement imposes on patients during the COVID-19 pandemic, discussed further *infra*, easily outweigh the government’s asserted interests here. *See* Pls.’ Reply 8-16; ECF No. 12 (“Pls.’ Opening Br.”) 7, 24-28.

Indeed, even under the test the concurrence posits, the illogic of requiring patients to travel in person to a health care facility, during a pandemic, solely to pick up a pill (which the FDA permits them to swallow, unsupervised, at home) and sign a form (which they have already reviewed with their clinician), is dispositive as to both Plaintiffs’ undue burden and equal

protection claims. The concurrence contends that, in applying the undue burden test, a law's "benefits" are relevant "in considering [a] threshold requirement that the State have a 'legitimate purpose'" for restricting abortion, and that the challenged law "be '*reasonably related to that goal.*'" *June Med. Servs.*, 2020 WL 3492640, at *25 (Roberts, C.J., concurring) (emphasis added) (citations omitted). Here, because the Mifepristone In-Person Dispensing Requirement does not bear any reasonable relationship to advancing patient safety during the COVID-19 pandemic, it is unconstitutional under any standard.

2. Cognizable Burdens

A robust body of case law, including *Whole Woman's Health*, forecloses Defendants' argument that the Constitution allows the government to freely burden medication abortion patients so long as they are ultimately still able to obtain an abortion. *See* Pls.' Reply 9; Defs.' Br. 12-15. *June Medical* adds to this jurisprudence, reinforcing that courts must consider an array of burdens short of outright prevention in evaluating Plaintiffs' constitutional claims. *See, e.g., June Med. Servs.*, 2020 WL 3492640, at *18 ("Those women not altogether prevented from obtaining an abortion would face other burdens"); *id.* at *6-7 (characterizing as "essential" the district court finding that "[t]hose who *can* [obtain an abortion] will face substantial obstacles in exercising their constitutional right to choose abortion" because of reduced availability (emphasis added)); *see also id.* at *27 (Roberts, C.J., concurring) (discussing burdens beyond prevention, including increased medical risk).

Defendants' contention that this Court should not consider the needless risk to which the Mifepristone In-Person Dispensing Requirement subjects patients as a condition of obtaining medication abortion care was meritless before *June Medical* and is all the more unavailing now. *See* Defs.' Br. 13-14, 20-21. Both the plurality and the concurrence recognized that, "[a]s in

Whole Woman's Health,” the Louisiana law would result in “longer waiting times, and increased crowding,” and the plurality explained that an expansion of services by one physician still “would not meaningfully address the health risks associated with crowding and delay.” *June Med. Servs.*, 2020 WL 3492640, at *18-19; *see also id.* at *27 (Roberts, C.J., concurring) (noting with approval that the district court in *June Medical*, like the Court in *Whole Woman's Health*, found that the law would result in “longer waiting times for appointments, increased crowding and increased associated health risk” (internal quotation marks and citations omitted)). The plurality likewise highlighted “that delays in obtaining an abortion increase the risk that a woman will experience complications from the procedure *and may make it impossible for her to choose a noninvasive medication abortion.*” *Id.* at *18 (emphasis added). And, as in *Whole Woman's Health*, the plurality emphasized the district court’s finding that “the burdens of this increased travel would fall disproportionately on poor women, who are least able to absorb them.” *Id.*; *accord* 136 S. Ct. at 2302 (highlighting district court’s finding that the Texas laws imposed particular burdens on “poor, rural, or disadvantaged women”).

The risks that travel, childcare, and in-person health care visits pose during the COVID-19 pandemic are so significant that Defendants have, *inter alia*, authorized controlled substances to be prescribed without the previously required in-person visit; permitted drugs subject to a REMS to be prescribed without the mandatory MRIs and lab testing; relaxed requirements for prescription drug samples to permit patients to receive such medication by mail or common carrier at their homes; and—as Plaintiffs and the Court learned for the first time at oral argument—allowed two *other* drugs subject to ETASU C to be dispensed at patients’ homes, instead of the in-person administration at health care facilities required by their REMS, during the pandemic. *See* Pls.’ Opening Br. 12-15; Pls.’ Reply 2; ECF No. 78, at 1-2. Defendants’

extensive efforts to mitigate transmission risks for patients using other drugs, and Plaintiffs’ un rebutted expert testimony, readily establish that subjecting patients to SARS-CoV-2 exposure risks as a condition of obtaining medication abortion care is a substantial obstacle indeed. This is particularly so for low-income people and people of color, who comprise the majority of abortion patients and who are more likely to suffer preexisting conditions that put them at higher risk of severe illness or death from COVID-19. *See* Pls.’ Opening Br. 20-24.

Recent events underscore the seriousness, pervasiveness, and duration of this risk. As states have begun to allow increased in-person contact, COVID-19 cases are surging. According to the CDC, a component of Defendant HHS, while the nationwide daily number of new COVID-19 cases had previously exceeded 35,000 only on two days in April—and otherwise generally remained below 30,000 since the beginning of the U.S. outbreak in March—the past week has seen record-breaking rates, on multiple days approaching 45,000 new cases.² These resurgences, which are consistent with Plaintiffs’ un rebutted expert testimony, *see* ECF No. 11-4, ¶¶ 12, 28, are emblematic of the ongoing and substantial risk that patients across the country face when forced to travel to and from a health care facility (involving, *e.g.*, public transportation, cabs, ride shares, and/or gas stations and rest stops); bring someone into their home to assist with childcare or drop their children off with others; and navigate in-person contact at a health care facility. *See* Pls.’ Opening Br. 19-24. *Even if* the undue burden test demanded a showing of “substantial obstacle” without regard to the strength of the government’s interest, the Requirement would still pose an unconstitutional undue burden during the pandemic because of the viral exposure risks it imposes as a condition of accessing abortion care.

² U.S. Ctrs. for Disease Control & Prevention, *Coronavirus Disease 2019 (COVID-19): Cases in the U.S.*, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html> (last visited July 1, 2020).

C. Remedy

June Medical also puts to rest Defendants’ argument that the In-Person Dispensing Requirement should be facially invalidated only if Plaintiffs show that it “is invalid in *all* circumstances.” Defs.’ Br. 12. In *June Medical*, the defendants cited *United States v. Salerno*, 481 U.S. at 745, arguing, as Defendants do here, that the law was not facially invalid because it did not burden “every woman.” *June Med. Servs.*, 2020 WL 3492640, at *21 (emphasis in original). The plurality responded that this was “[t]rue, but beside the point,” because, as the Court previously held in both *Casey* and *Whole Woman’s Health*, a restriction on access to abortion is facially invalid when it operates unconstitutionally in “a large fraction of cases in which [it] is relevant.” *Id.* (quoting *Planned Parenthood Se. Pa. v. Casey*, 505 U.S. 833, 895 (1992)). “That standard, not an ‘every woman’ standard, is the standard that must govern in this case.” *Id.*³

D. CONCLUSION

In *June Medical*, the Supreme Court invalidated once again a purported safety regulation that burdens abortion patients without sufficient countervailing benefit. Plaintiffs and their *amici*—the nation’s health care providers—respectfully ask this Court to do the same, enjoining this singular restriction on abortion and miscarriage care during the COVID-19 pandemic.

³ As Plaintiffs have previously explained, they easily satisfy the large fraction test for facial relief. *See* Pls.’ Reply 15-16. Plaintiffs note, however, that as the Court suggested during oral argument, because the requested relief is limited in duration, it could also be understood as a request for as-applied relief.

Respectfully submitted,

/s/ Julia Kaye

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with
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